REMARKS

Rejection under 35 U.S.C § 103 – Obviousness

Summary

The Examiner issued a 35 U.S.C § 103(a) rejection of claims 1, 6, 9-11, 14, 17, 18 and 20-22 as being unpatentable over U.S. Pat. No. 5,865,723 to Love (Love) in view of U.S. Pat. No. 5,891,193 to Robinson et al. (Robinson et al.); rejection of claims 4, 5, 7 and 8 as being unpatentable over Love in view of Robinson et al. and further in view of U.S. Pat. No. 6,358,284 B1 to Fearnot et al. (Fearnot et al.); and rejection of claims 1, 12 and 16 as being unpatentable over U.S. Pat. No. 5,628,788 to Pinchuk (Pinchuk) in view of Fearnot et al.

Applicants disagree with the Examiner's rejections for reasons described below.

Claims 1, 2, 6, 9-11, 14, 17 and 18 are directed to stent tissue graft prostheses that include: i) a first expandable stent having a first distal stent end and a first proximal stent end, a tubular wall and a passage extending longitudinally therethrough; ii) a tissue graft having a distal tissue graft end and a proximal tissue graft end and disposed on said first stent; and iii) a tubular member having a wall and a passage extending longitudinally therethrough, said tubular member being disposed over said tissue graft and around said first stent and retaining said tissue graft disposed on said first stent. A most distal end of the first distal stent end is at least coincident with a most distal end of the distal tissue graft end and a most proximal end of the first proximal stent end is at least coincident with a most proximal end of the proximal tissue graft end to prevent the tissue graft from everting or folding into the passage of the first expandable stent.

The independent claim 20 is directed to a stent tissue graft prosthesis that includes: i) a first expandable stent having a first distal stent end and a first proximal stent end, a tubular wall and a passage extending longitudinally therethrough; ii) a multilayered tissue graft construct having a distal construct end and a proximal construct end, a tubular wall and a passage extending longitudinally therethrough and disposed on said first stent; and iii) a second expandable stent having a tubular wall and

a passage extending longitudinally therethrough, said second stent being disposed over and around said construct and said first stent, and retaining said construct disposed on said first stent. A most distal end of the first distal stent end is at least coincident with a most distal end of the distal construct end and a most proximal end of the first proximal stent end is at least coincident with a most proximal end of the proximal construct end to prevent the multilayered tissue graft from everting or folding into the passage of the first expandable stent.

Claims 21 and 22 are also directed to stent tissue graft prostheses. However, the most distal end of the first distal stent end of the prostheses extends beyond the most distal end of the distal tissue graft end (claim 21) or the construct end (claim 22) and the most proximal end of the first proximal stent end of the prostheses extends beyond a most proximal end of the proximal tissue graft end (claim 21) or construct end (claim 22) to prevent the tissue graft (claim 21) or the multilayered tissue graft (claim 22) from everting or folding into the passage of the first expandable stent.

Argument for Claims 1, 6, 9-11, 14, 17, 18 and 20-22

The Examiner rejected claims 1, 6, 9-11, 14, 17, 18 and 20-22 as being unpatentable over Love in view of Robinson et al. Specifically, the Examiner asserted that although Love does not disclose that the distal and proximal most portions of the first stent are at least coincident with or extend beyond the distal and proximal most ends of the graft, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the implant of Love to have stent anchor extensions that extend beyond the graft ends, because (1) Robinson et al. teaches an inner extendable stent member having anchors that extend beyond the graft distal and proximal ends, and (2) the tubular implant taught by Robinson et al. is in the same field of endeavor.

At the outset, Applicants point out that at page 11, lines 10-19 of the instant specification, Applicants teach that the distal and proximal ends of tissue graft *need to be coincident with the ends of the inner stent to prevent the tissue graft from folding*

over or inverting into passage of the inner stent during pulsatile flow of blood when the prosthesis is positioned in a blood vessel. The fold-over or eversion, as further taught by the Applicants, can cause turbulent blood flow and can clearly create lumen restriction for thrombus to build up on and further restrict the blood flow (see specification at page 11, lines 10-19).

The Examiner argues that "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to make the implant of Love have stent anchor extensions that extend beyond the graft ends as taught by Robinson [et al.] in order to better anchor the implant to the vessel" (Office action dated November 19, 2007, page 3, lines 10-13). However, there would have been absolutely no motivation or reason to modify the cited Love reference in order to arrive at the claimed devices inasmuch as neither of the applied references even acknowledges or recognizes that the distal and proximal ends of tissue graft *need to be at least coincident with the ends of the inner stent to prevent the tissue graft from everting or folding into the passage of the first expandable stent* during pulsatile flow of blood when the prosthesis is positioned in a blood vessel. This teaching is only found in Applicants' disclosure and, in accordance with MPEP 2143, cannot provide the basis for a motivation to modify or combine references.

In fact, contrary to the Examiner's assertion, it would not have been obvious to combine the Love and Robinson et al. references to arrive at the prosthesis of the present invention because Love actually **teaches away from** Applicants' invention. For example, at column 6, lines 40-46, Love teaches specifically that:

> "... The rolled **tissue** supported by the frame will often **extend** slightly **beyond** the ends of the frame (...). Such **tissue extensions** can facilitate suturing of the prosthesis to form end-to-end and end-to-side anastomoses in performing [coronary artery bypass graft] CABG and other procedures." (Emphases added)

In addition, Figures 6-9 of the Love reference clearly illustrate the tissue extending beyond the ends of the inner stent. Because Love clearly teaches that tissue should extend beyond the inner stent/frame to facilitate suturing, one would be

dissuaded to alter the prosthesis of Love to make the ends of the stent and graft at least coincident (or extend beyond the graft ends), as taught by Robinson et al.

Furthermore, in the recent *KSR* case the Supreme Court stated that it is "...important to **identify a reason** that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex, Inc.*, 82USPQ2d 1385, 1389 (2007) (emphasis added) In this instance, one would not have a reason to combine the Love and Robinson et al. references to arrive at the Applicants' invention because folding-over or eversion of tissue into the passageway of the inner stent upon implantation into a blood vessel is never identified as a potential problem associated with the device of Love. In fact, Love specifically teaches that it is preferred to have the ends of the tissue extend beyond the ends of the frame (i.e., inner stent) to facilitate suturing to form end-to-end and end-to-side anastomoses during surgical procedures (Love, column 6, lines 40-46). Thus, one would not have a reason to modify the device of Love by applying teachings of Robinson et al.

Clearly, Applicants' invention of claims 1, 6, 9-11, 14, 17, 18 and 20-22 would not have been obvious in view of the Love and Robinson et al. references. Consequently, Applicants request that the 35 U.S.C § 103(a) rejection of claims 1, 6, 9-11, 14, 17, 18 and 20-22 as being unpatentable over Love in view of Robinson et al. be withdrawn.

Argument for Claims 4, 5, 7 and 8

The Examiner rejected claims 4, 5, 7 and 8 as being unpatentable over Love in view of Robinson et al. and further in view of Fearnot et al.

As discussed above, because the Love reference teaches away from the invention of claim 1 and because one of ordinary skill in the art would not have a reason to modify the prosthesis of Love to have the stent and graft ends coincide, as taught by Robinson et al., the invention of independent claim 1 would not have been obvious.

Furthermore, the Fearnot et al. reference does not provide a reason to modify the prosthesis of Love to include an inner stent with the most proximal and most distal ends

being are at least coincident with the most proximal and most distal graft ends, respectively, as taught by Robinson et al.

Because the stent tissue graft prosthesis of Applicants' claims 1 is both novel and non-obvious, the prostheses defined by the claims depending on claim 1, are also novel and non-obvious. In particular, claims 4, 5, 7 and 8 are not obvious under 35 U.S.C. §103 over Love in view of Robinson et al. and further in view of Fearnot et al. Applicants request that the obviousness rejection of claims 4, 5, 7 and 8 be withdrawn.

Argument for Claims 1, 12 and 16

The Examiner also rejected claims 1, 12 and 16 as being unpatentable over Pinchuk in view of Fearnot et al. Specifically, the Examiner asserted that "Pinchuk discloses invention substantially as claimed being a double-layered stent graft wherein the inner stent is smaller than the outer stent and the ends of each layer are at least coincident as seen in figures 3-9 [of Pinchuk]" (Office action dated November 19, 2007, page 4, lines 8-11). The Examiner further asserts that "Fearnot teaches the use of tubular grafts comprising layers of submucosa tissue sheets in the same endeavor for the purpose of providing enhanced repair of damaged or diseased host tissue" (Office action dated November 19, 2007, page 4, lines 12-14).

Applicants disagree.

Applicants have previously argued[1] and convinced the Examiner[2] that neither the text of the specification nor the figures, including figures 3-9, of the Pinchuk reference actually teach or show stent tissue graft prostheses that include a *first (inner) stent with ends that are at least coincident with the ends of a tissue graft.*

Although, in the current Office action, the Examiner asserted that figures 3-9 of Pinchuk show that the distal and proximal ends of the stent coincide with the distal and

[1] Applicants' arguments presented at pages 10-13 of Amendment and Response filed on April 25, 2007 together with a request for continued examination and after issuance of final Office action dated March 12, 2007 are incorporated herein by reference.
[2] The Examiner asserted that Pinchuk ***does not teach*** that the distal and proximal most portions of the first sent are coincident with the distal and proximal ends of the graft (see Office action dated June 22, 2007 at page 5, lines 4-8).

proximal ends of the tissue graft, respectively, Applicants again respectfully point out that none of the figures of Pinchuk actually illustrate stent tissue graft prostheses where both, the proximal and distal ends of the *inner* stent are coincident with the ends of the tissue graft to prevent the tissue graft from everting or folding into the passage of the first expandable stent. "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.,* 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Specifically, figures 3-6 do not illustrate Applicants' prostheses. Rather, figures 3 and 4 of Pinchuk illustrate a graft (textile tube) and figures 5 and 6 illustrate a stent graft (stent over graft).

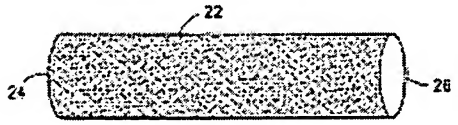

FIG. 3
GRAFT

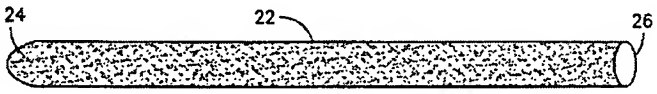

FIG. 4
GRAFT

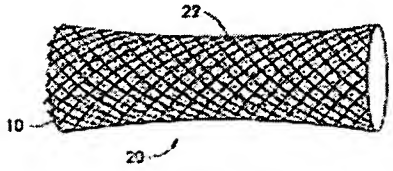

FIG. 5

STENT GRAFT

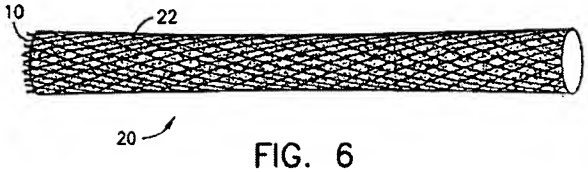

FIG. 6

STENT GRAFT

Similarly, figures 7-9 do not show Applicants' invention. Rather, figures 7-9 of Pinchuk are cross-sectional views of various exemplary stent graft configurations and illustrate only small *portions* of the actual devices. Because there is no specific teaching in the text of the specification of Pinchuk that the ends of the inner stent 10 at least coincide with the ends of the graft 22, and figures 7-9 illustrate only small *portions* of the actual devices (rather than entire device), one of skill in the art would not

conclude that the figures of the Pinchuk reference teach or suggest ends of the *inner* stent coinciding with the ends of the graft.

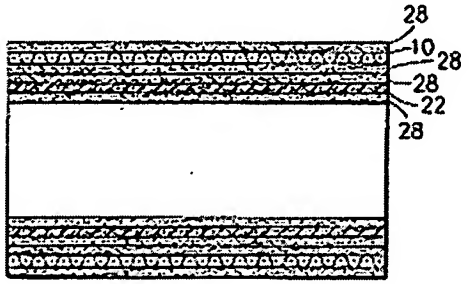

FIG. 7

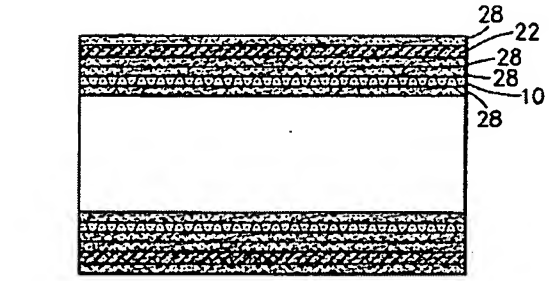

FIG. 8

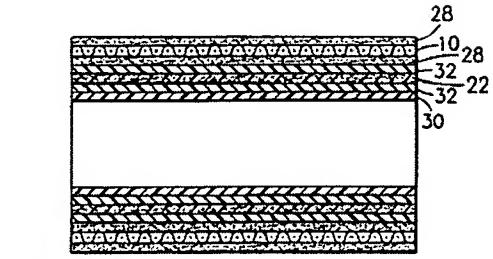

FIG. 9

Although, the Pinchuk reference states that the inner stent may be included with the devices of some other figures, which were not mentioned by the Examiner (figures 13-18), there is no teaching or suggestion whatsoever in the Pinchuk reference of ends of the *inner* stent being *at least coincident with the ends of the graft.* Clearly there is no teaching or suggestion whatsoever in the Pinchuk reference of all the elements of Applicants' claims 1, 12, and 16.

Furthermore, nothing in the Fearnot et al., reference suggests modifying the prosthesis of Love or Pinchuk to include *an inner stent with ends that are at least coincident with the ends of a tissue graft* to prevent the tissue graft from everting or folding into the passage of the first expandable stent.

In view of the above remarks, it would not have been obvious to one of skill in the art to combine the Pinchuk and Fearnot et al. references to arrive at the invention of claim 1. Because the stent tissue graft prosthesis of Applicants' claims 1 is both novel and non-obvious, the prostheses defined by the claims depending on claim 1, are also

novel and non-obvious. In particular, claims 12 and 16 are not obvious under 35 U.S.C. §103 over Pinchuk in view of Fearnot et al. Accordingly, Applicants request that the obviousness rejection of claims 1, 12 and 16 be withdrawn.

Additional Remarks

Also, based on the two primary references (Love and Pinchuk) provided by the Examiner, it seems that, generally, the prior art did not appreciate the advantages of having the ends of the inner stent at least coincide with the ends of the graft material in a device that includes graft material between, for example, two stents. Indeed, the invention of independent claim 1 is that the device has the inner stent ends coincide with or are longer than the graft ends so that the tissue graft would not evert or fold into the passage.

Applicants request that the 35 U.S.C § 103(a) rejection of claims 1, 6, 9-11, 14, 17, 18 and 20-22 as being unpatentable over Love in view of Robinson et al.; rejection of claims 4, 5, 7 and 8 as being unpatentable over Love in view of Robinson et al. and further in view of Fearnot et al.; and rejection of claims 1, 12 and 16 as being unpatentable over Pinchuk in view of Fearnot et al. be withdrawn.

SUMMARY

Applicants respectfully submit that the present application is now in condition for allowance. If, for any reason, the Examiner feels a discussion would expedite the prosecution of this application, the Examiner is kindly invited to contact the undersigned at (312) 245-5398.

Respectfully submitted,

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